



PATIENT INFORMATION

<b>PATIENT:</b> John Doe	<b>DOB:</b> 01 Jan 1973	<b>GENDER:</b> M	<b>LAB ID:</b> L123	<b>MRN:</b> M123
<b>COLLECTION DATE</b> 03 Jun 2018	<b>FACILITY NAME</b> University Hospital of Anytown			
<b>RECEIVED DATE</b> 05 Jun 2018	<b>SUBMITTING PHYSICIAN</b> Jane Demo	<b>PHONE</b> (555) 555-5555		
<b>REPORT DATE</b> 06 Jun 2018	<b>TREATING PHYSICIAN/CC</b> ---	<b>PHONE</b> ---		

CLINICAL HISTORY: No Clinical History Provided

RESULTS SUMMARY

NODULE	CYTOPATHOLOGY	AFIRMA GSC	MALIGNANCY CLASSIFIERS	XPRESSION ATLAS	
A	---	Benign (ROM 4% <sup>1</sup> )	Negative	N/A	

RESULTS DETAILS

<b>NODULE A</b>	<b>SIZE:</b> 1.5 cm	<b>LOCATION:</b> Upper Right
<b>AFIRMA GSC RESULT</b>	Benign	
<b>MALIGNANCY CLASSIFIERS RESULTS</b>	<b>Negative:</b> <i>BRAF</i> p. V600E c. 1799T>A, MTC <b>Not Detected:</b> <i>RET/PTC1</i> , <i>RET/PTC3</i>	
<b>MALIGNANCY CLASSIFIERS COMMENTS</b>	MTC and <i>BRAF</i> malignancy classifier results were negative and <i>RET/PTC1</i> and <i>RET/PTC3</i> were not detected. These results do not change the risk of malignancy (ROM) of the Afirma GSC Benign result.	
<b>GROSS DESCRIPTION</b>	Received one vial of FNAProtect, labeled with the Requisition Form # and patient initials.	

RESULTS INTERPRETATION

Afirma GSC <sup>1,5</sup>	Cytopathology Diagnosis Indeterminate <sup>§</sup>	Malignancy Classifiers			Parathyroid <sup>6,8</sup>
		MTC <sup>3,8</sup>	<i>BRAF</i> <sup>†2,4,8</sup>	<i>RET/PTC</i> <sup>2,8</sup>	
Risk of Malignancy: <b>Afirma GSC Benign</b>	4%	>99% / >99%	>99% / >99%	>99% / >99%	>99% / >99%
Risk of Malignancy: <b>Afirma GSC Suspicious</b>	~50%	PPA/NPA	>99% / >99%	>99% / >99%	
Sensitivity:	91%	Confirmation Rate/NPA	>99% / >99%	>99% / >99%	
Specificity:	68%	Risk of Malignancy	>99%	>95%	
Limit of Detection <sup>†</sup> :	5%	Limit of Detection <sup>†</sup>	20%	5%	10%

References: 1. Patel KN, et al. WCTC 2017. 2. Haugen BR, et al. *Thyroid* 2016. 3. Randolph G, et al. ATA 2017. 4. Angell TE, et al. ATA 2017. 5. Hu Z, et al. ATA 2017. 6. Sosa JA, et al. ATA 2017. 8. Data on file.

§ Indeterminate includes Atypia of Undetermined Significance / Follicular Lesion of Undetermined Significance and (suspicious for) Follicular Neoplasm / Hürthle Cell Neoplasm.

<sup>†</sup> Analytical sensitivity studies demonstrated the test's ability to detect malignant cells in a background of benign cells.

<sup>‡</sup> *BRAF* classifier performance is based on a comparison to a castPCR DNA assay for the *BRAF* V600E mutation.

Afirma Thyroid FNA Analysis is a diagnostic service provided by Veracyte, Inc. for the assessment of thyroid nodules that includes cytopathology and gene expression testing. Afirma GSC, *BRAF*, MTC and *RET/PTC* tests and their performance characteristics were determined by Veracyte. MTC is an RNA classifier that identifies the presence of medullary thyroid carcinoma (MTC); *BRAF* is a *BRAF* p. V600E, c. 1799T>A RNA classifier; *RET/PTC* is a gene expression marker of somatic rearrangements of the *RET* protooncogene (*RET/PTC1* and *RET/PTC3*).

E-SIGNED ON 06 Jun 2018 10:43 AM BY:

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Lab Director: Robert J Monroe, MD, PhD

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<b>CLINICAL HISTORY:</b> History of Cancer: No, Family History of Thyroid Cancer: No, History of I(131)radiation or external radiation therapy: No				

RESULTS SUMMARY

NODULE	CYTOPATHOLOGY	AFIRMA GSC	MALIGNANCY CLASSIFIERS	XPRESSION ATLAS	ISTHMUS
A	---	Suspicious (ROM ~50% <sup>1</sup> )	Negative	Not Detected	

See Xpression Atlas results overview page for additional information

RESULTS DETAILS

<b>NODULE A</b>	<b>SIZE:</b> 1.1 cm	<b>LOCATION:</b> Upper Right
<b>AFIRMA GSC RESULT</b>	Suspicious	
<b>MALIGNANCY CLASSIFIERS RESULTS</b>	<b>Negative:</b> BRAF p. V600E c. 1799T>A, MTC <b>Not Detected:</b> RET/PTC1, RET/PTC3	
<b>MALIGNANCY CLASSIFIERS COMMENTS</b>	MTC and BRAF malignancy classifier results were negative and RET/PTC1 and RET/PTC3 were not detected. These results do not change the risk of malignancy (ROM) of the Afirma GSC Suspicious result.	
<b>GROSS DESCRIPTION</b>	Received one vial of FNAProtect, labeled with the Requisition Form # and patient initials.	

RESULTS INTERPRETATION

Afirma GSC <sup>1,5</sup>	Cytopathology Diagnosis Indeterminate <sup>5</sup>	Malignancy Classifiers	Parathyroid <sup>5,8</sup>
Risk of Malignancy: Afirma GSC Benign	4%	MTC <sup>3,8</sup>	>99% / >99%
Risk of Malignancy: Afirma GSC Suspicious	~50%	BRAF <sup>2,4,8</sup>	>99% / >99%
Sensitivity:	91%	RET/PTC <sup>2,8</sup>	>99% / >99%
Specificity:	68%		>95%
Limit of Detection <sup>1</sup> :	5%		10%
Sensitivity/Specificity PPA/NPA		>99% / >99%	
Confirmation Rate/NPA		>99% / >99%	
Risk of Malignancy		>99%	
Limit of Detection <sup>1</sup>		20%	15%

References: 1. Patel KN, et al. WCTC 2017. 2. Haugen BR, et al. Thyroid 2016. 3. Randolph G, et al. ATA 2017. 4. Angell TE, et al. ATA 2017. 5. Hu Z, et al. ATA 2017. 6. Sosa JA, et al. ATA 2017. 8. Data on file.

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